Notice of Allowability	Application No. 10/536,880	Applicant(s) ONOUE ET AL.	
	Examiner Julie Ha	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment after Non-final rejection filed on July26, 2007*.

2. ☒ The allowed claim(s) is/are *1-11 and 13-19*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ----------
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

4/12/07
ANISH GUPTA
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with David P. Stizel on September 13, 2007.

3. New claims 17-19 have been added. Claims 1-11 and 13-19 are allowed.

4. The application has been amended as follows:

Claim 1 A peptide comprising at least 23 amino acid residues from the N-terminal of the peptide, or a pharmaceutically acceptable salt thereof, according to formula (I):

His-Ser-Asp-Ala-variable A-Phe-Thr-variable B-variable C-Tyr-variable D-Arg-variable E-Arg-variable F-Gln-variable G-Ala-Val-variable H-variable I-Tyr-Leu-Ala-Ala-variable J-variable K-variable L (SEQ ID NO: 1) (I)

wherein variable A represents Val or Ile; variable B represents Asp, Glu, or Ala; variable C represents Asn or Ser; variable D represents Thr or Ser; variable E represents Leu or Tyr; variables F, H, and I each independently represent Lys or Arg; variable G represents Leu or Nle; variable J represents Ile or Val; variable K represents

Leu, Leu-Asn, Leu-Gly, Leu-Gly-Lys, Leu-Gly-Arg, Leu-Gly-Lys-Lys, Leu-Gly-Lys-Arg, Leu-Gly-Arg-Arg, Leu-Gly-Lys-Arg-Tyr-Lys-Gln-Arg-Val-Lys-Asn-Lys, or Leu-Gly-Arg-Arg-Tyr-Arg-Gln-Arg-Val-Arg-Asn-Arg; and variable L represents a moiety attached to the α-carboxyl group of the C-terminal amino acid, wherein said moiety is an $-NH_2$ or -OH.

Claim 2 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 1, which consists of 23 amino acid residues from the N-terminus of the peptide according to formula (I), wherein variable A represents Val; variable B represents Asp; variable C represents Asn; variable D represents Thr; variable E represents Leu; variables F, H, and I each independently represent Arg; variable G represents Leu; and variable L represents an $-NH_2$ moiety attached to the α-carboxyl group of the C-terminal amino acid.

Claim 3 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 14, wherein variable A represents Val; variable B represents Asp; variable C represents Asn; variable D represents Thr; variable E represents Leu; and variable J represents Ile.

Claim 4 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 14, wherein variable A represents Val; variable B represents Glu;

variable C represents Asn; variable D represents Thr; variable E represents Leu; and variable J represents Ile.

Claim 5 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 14, wherein variable A represents Val; variable B represents Ala; variable C represents Asn; variable D represents Thr; variable E represents Leu; and variable J represents Ile.

Claim 6 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 14, wherein variable A represents Val; variable B represents Asp; variable C represents Asn; variable D represents Thr; variable E represents Leu; and variable J represents Val.

Claim 7 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 14, wherein variable A represents Ile; variable B represents Asp; variable C represents Ser; variable D represents Ser; variable E represents Tyr; and variable J represents Val.

Claim 8 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 1, wherein variable A represents Ile; variable B represents Asp; variable C represents Ser; variable D represents Ser; variable E represents Tyr; variables F, H, and I each independently represent Arg; variable G represents Leu;

variable J represents Val; variable K represents Leu-Gly-Arg-Arg-Tyr-Arg-Gln-Arg-Val-Arg-Asn-Arg; and variable L represents an $-NH_2$ moiety attached to the α-carboxyl group of the C-terminal amino acid.

Claim 9 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 1, which consists of 23 amino acid residues from the N-terminus of the peptide according to formula (I), wherein variable A represents Ile; variable B represents Asp; variable C represents Ser; variable D represents Ser; variable E represents Tyr; variables F, H, and I each independently represent Arg; variable G represents Leu; and variable L represents an $-NH_2$ moiety attached to the α-carboxyl group of the C-terminal amino acid.

Claim 10 A pharmaceutical composition comprising one or more biologically active peptides according to claim 1, ~~wherein said one or more biologically active peptides include the peptide~~, or a pharmaceutically acceptable salt thereof ~~according to claim 1~~.

Claim 11 A pharmaceutical composition comprising one or more biologically active peptides according to claim 1, ~~wherein said one or more biologically active peptides include the peptide~~, or a pharmaceutically acceptable salt thereof, ~~according to claim 1,~~ which is present as an active ingredient within the pharmaceutical composition

in an amount of at least 50% by weight based on the total weight percent of the biologically active peptides contained within the pharmaceutical composition.

Claim 13 A method of ~~treating or preventing one or more diseases or symptoms selected from the group consisting of ischemic cerebrovascular disorders including cerebral embolism and cerebral thrombosis, diseases causing toxicity to the central or peripheral nervous system, cerebrovascular ischemia, thrombosis, conformational diseases, neurodegenerative diseases, hair loss, erectile dysfunction, dementia, kidney failure, optic nerve degenerative diseases including atrophy of optic nerve and ischemic optic neuropathy, and retinal degenerative diseases, of improving blood flow, of~~ relaxing the bronchial smooth muscle, ~~or of inhibiting the movement in the gastrointestinal tract,~~ wherein said method comprises administering to a patient in need thereof a therapeutically effective amount of the peptide according to claim 1, or a pharmaceutically acceptable salt thereof~~, according to claim 1~~.

Claim 14 The peptide, or a pharmaceutically acceptable salt thereof, according to claim 1, wherein variables F, H, and I each independently represent Arg; variable G represents Leu; variable K represents Leu-Gly-Arg-Arg; and variable L represents an $-NH_2$ moiety attached to the α-carboxyl group of the C-terminal amino acid.

Claim 15 A method of ~~treating one or more diseases or symptoms selected from the group consisting of ischemic cerebrovascular disorders including cerebral embolism and cerebral thrombosis, diseases causing toxicity to the central or peripheral nervous system, cerebrovascular ischemia, thrombosis, conformational diseases, neurodegenerative diseases, hair loss, erectile dysfunction, dementia, kidney failure, optic nerve degenerative diseases including atrophy of optic nerve and ischemic optic neuropathy, and retinal degenerative diseases, of improving blood flow, of~~ relaxing the bronchial smooth muscle, ~~or of inhibiting the movement in the gastrointestinal tract,~~ wherein said method comprises administering to a patient in need thereof a therapeutically effective amount of the pharmaceutical composition according to claim 10.

Claim 16 A method of ~~treating one or more diseases or symptoms selected from the group consisting of ischemic cerebrovascular disorders including cerebral embolism and cerebral thrombosis, diseases causing toxicity to the central or peripheral nervous system, cerebrovascular ischemia, thrombosis, conformational diseases, neurodegenerative diseases, hair loss, erectile dysfunction, dementia, kidney failure, optic nerve degenerative diseases including atrophy of optic nerve and ischemic optic neuropathy, and retinal degenerative diseases, of improving blood flow, of~~ relaxing the bronchial smooth muscle, ~~or of inhibiting the movement in the gastrointestinal tract,~~ wherein said method comprises administering to a patient in need thereof a

therapeutically effective amount of the pharmaceutical composition according to claim 11.

Claim 17 A method of inhibiting the movement in the gastrointestinal tract, wherein said method comprises administering to a patient in need thereof a therapeutically effective amount of the peptide according to claim 1, or a pharmaceutically acceptable salt thereof~~, according to claim 1~~.

Claim 18 A method of inhibiting the movement in the gastrointestinal tract, wherein said method comprises administering to a patient in need thereof a therapeutically effective amount of the pharmaceutical composition according to claim 10.

Claim 19 A method of inhibiting the movement in the gastrointestinal tract, wherein said method comprises administering to a patient in need thereof a therapeutically effective amount of the pharmaceutical composition according to claim 11.

Conclusion

5. The claimed peptide and its compositions are both novel and unobvious over the prior art of record. Claims 1-11 and 13-19 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

9/11/07
ANISH GUPTA
PRIMARY EXAMINER